RESULTS OF INVESTIGATION: Examination of the *amobarbital sodium* showed that some ampuls contained more and some ampuls contained less than the labeled amount of amobarbital sodium. Examination of the *phenobarbital sodium* showed that it contained more than the labeled amount of that ingredient.

CHARGE: *Phenobarbital sodium.* 501 (b)—the article purported to be and was represented as "Sterile Phenobarbital Sodium," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium; and its strength, when shipped, differed from the official standard since the average weight of the content of phenobarbital sodium per ampul failed to comply with the standard specified in the compendium.

Amobarbital sodium. 501 (b)—the article purported to be and was represented as "Amobarbital Sodium," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength, when shipped, differed from the official standard since the average weight of the content of *Amobarbital Sodium* per ampul failed to comply with the standard specified in the compendium; and 502 (d)—the article contained amobarbital sodium, a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and the label of the article failed to bear the statement "Warning—May be habit forming."

PLEA: Guilty.

DISPOSITION: 6–17–57. Defendant fined $2,000 and placed on probation for 3 years.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

5328. Serutan. (F. D. C. No. 39807. S. Nos. 35–501 M, 35–504 M.)

QUANTITY: 24 doz. boxes, 9 oz. each, at Cincinnati, Ohio.

SHIPPED: Between 4–1–56 and 9–28–56, from Newark, N. J.

LIBELED: 12–6–56, S. Dist. Ohio.

CHARGE: 501 (a) (2)—contained insects while held for sale.

DISPOSITION: 1–11–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5329. Digitalis tablets. (F. D. C. No. 40163. S. No. 35–064 M.)

QUANTITY: 1 drum containing 67,300 tablets at Cleveland, Ohio.

SHIPPED: 8–3–56, from New York, N. Y.

LABEL IN PART: (Drum) "Tablets Digitalis Leaves Private Formula #1078 U. S. P. 1½ gr. * * * 17214 The Superior Pharmacal Co., Dayton, Ohio."

RESULTS OF INVESTIGATION: The article was shipped from New York, N. Y., as a bulk powder; and, after receipt in Dayton, Ohio, it was made into tablets by Superior Pharmacal Co. and shipped to Cleveland, Ohio. Examination showed that the tablets contained not more than 67.6 percent of the declared amount of digitalis, or 1.01 grains of U. S. P. digitalis per tablet. The United States Pharmacopeia provides that digitalis tablets contain the labeled amount of digitalis.

LIBELED: 4–11–57, N. Dist. Ohio.

*See also Nos. 5324, 5326, 5327, 5338, 5340.

CHARGE: 501 (b)—the article, while held for sale, purported to be a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 5–13–57. Default—destruction.

5330. Digitoxin powder. (F. D. C. No. 40111. S. No. 56–160 M.)

QUANTITY: 2 25-gram btls. at Chicago, Ill.

SHIPPED: 1–16–57, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * Assay: Digitoxin 99.10% Loss on drying 0.62%."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 85 percent of digitoxin when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent.

LIBELED: 3–28–57, N. Dist. Ill.

CHARGE: 501 (b)—The article, when shipped, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4–23–57. Default—destruction.

5331. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40121. S. Nos. 38–204/5 M.)

QUANTITY: 1 6-gram btl. and 1 40,000-tablet drum at St. Louis, Mo.

SHIPPED: 12–14–56, from New York, N. Y., by H. Reisman Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking"; (drum) "0.2 mg. C. T. Digitoxin."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from a portion of the bulk *digitoxin powder* shipped on the above date.

Examination showed that the powder contained not more than 83.5 percent digitoxin and that the tablets contained not more than 0.156 milligram of digitoxin per tablet when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay results be not less than 90 percent of the labeled amount of digitoxin.

LIBELED: 4–4–57, E. Dist. Mo.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4–30–57. Default—destruction.

5332. Digitoxin tablets. (F. D. C. No. 40162. S. No. 38–211 M.)

QUANTITY: 34,772 tablets at St. Louis, Mo.

SHIPPED: 7–6–56 and 11–26–56, from New York, N. Y.

LABEL IN PART: "109a Compressed Tablets Digitoxin, 0.2 mg. Each Tablet Contains: Digitoxin, U. S. P. * * * 0.2 mg."